

REMARKS

Claims 1-61, 64-94, 96-129, 132-139, 142-145, 147-150, 164 and 166-168 were pending. The Examiner allowed claims 1-56 and rejected the remaining claims. Applicant respectfully traverses the Examiner's rejection.

At the top of page 2 of the Office Action, the Examiner objected to the submission establishing the assignee's ownership indicating that the person who signed that submission was not recognized as an officer of the assignee and has not been authorized to act on behalf of the assignee. The Examiner then requested a new submission establishing the assignee ownership interest including a statement that the person is empowered to sign a submission establishing ownership interest and/or act on behalf of the organization. Accordingly, submitted with this response is the requested document establishing authority to act.

At the bottom of page 2 of the Office Action, and the top of page 3 of the Office Action, the Examiner rejected the non-allowed claims under 35 U.S.C. §251 as being improperly broadened. In a telephone discussion with the Examiner dated August 10, 2001, it was clarified that this rejection was based on recapture. In the Office Action, the Examiner stated that "the fact that the puncturing element was substantially non-parallel with respect to a portion of the catheter when in the puncturing position..." was introduced into the claims of the parent application by amendment filed March 2, 1994 and was not in the independent claims which are currently rejected. The Examiner also stated that the "restraint" limitation was placed in the independent claims by amendment filed March 23, 1995, and the Examiner indicated that the rejected claims were improperly broadened by not including this limitation as well. Applicant respectfully traverses this rejection.

With respect to the "restraint" limitation, Applicant submits that the recapture rule does not apply and should not bar claims with that subject matter omitted. The recapture rule only relates to limitations in the original claims which were:

"originally argued in the original application to make the application claims allowable over a rejection or objection made in the application...The argument that the claimed limitation defined over the rejection must have been specific as to the limitations; rather than a general statement regarding the claims as a whole. In other words, a general "boiler plate" sentence will not be sufficient to establish recapture. An example of one such "boiler plate" sentence is :In closing, it is argued that the limitations of claims 1-7 distinguish the claims from the teaching of the prior art, and claims 1-7 are thus patentable. This type of general "argument" will not, by itself, be sufficient to establish surrender and recapture." MPEP §1412.02.

With respect to the "restraint" limitation, the only argument pointed to by the Examiner states "Applicants believe that this case can be expedited by entering the requested claim amendments." Thus, Applicant submits that this general type of discussion does not invoke the recapture rule. Applicant thus submits that the "restraint" limitation is not required in the reissue claims.

With respect to the "non-parallel" limitation, Applicant submits that independent claims 57, 86, 91, 103, 120, 125, 132, 142, and 143 already claim this limitation. Those claims indicate that the tissue penetrating member has a tissue penetrating tip "disposed at an angle relative to the catheter body, the angle opening in a proximal direction of no more than approximately 90 degrees...". Since the angle "opens", it cannot be zero degrees. Similarly, since the angle is "no more than approximately 90 degrees" it must be non-parallel to the portion of the catheter body which contains the tissue penetrating member. Each of the claims mentioned above indicate that the angle is either relative to the catheter body, or relative to an

axis of the catheter body. Thus, Applicant submits that each of these claims already includes the "non-parallel" limitation cited by the Examiner.

It should also be noted that independent claim 147 already states "the tissue penetrating member moves from one of the first or second positions in a direction substantially non-parallel to the catheter body to the other of the first or second positions...". Thus, Applicant submits that claim 147 already contains the limitation mentioned by the Examiner.

In addition, claims 74, 82, 110, 116 and 147 have been amended to include similar limitations. For example, it will be noted that, in original claim 17 of the issued patent, the "non-parallel" limitation reads as follows:

"to move said puncturing element in a direction substantially non-parallel with respect to a portion of said catheter that contains said puncturing element...". Claim 74, 82, 110 and 116 have been amended to contain this limitation.

In conclusion, Applicant submits that claims 57-61, 64-94, 96-129, 132-139, 142-145, 147-150, 164 and 166-168 are now in allowable form. Applicant also acknowledges the Examiner's indication that claims 1-56 are allowable. Applicant will also submit a final Declaration of the inventors upon receiving an indication that the claims are otherwise allowable. Favorable action is respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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MARKED-UP VERSION OF REPLACEMENT CLAIMS

57. (Amended) An intravascular therapeutic catheter comprising:
an elongate catheter body having a distal portion;
a tissue penetrating member having a tissue penetrating tip,
disposed at an angle relative to the catheter body, the
angle opening in a proximal direction of no more than
approximately 90 degrees, the tissue penetrating member
being disposed proximate the distal portion, operably
coupled to the elongate catheter body, and having a
first non-penetrating position and a second tissue
penetrating position; and
an actuator member disposed proximate the distal portion and
operably coupled to the tissue penetrating member, for
moving the tissue penetrating member from one of the
first or second positions to the other of the first or
second positions, the actuator adding energy to the
tissue penetrating member as the tissue penetrating
member moves from the first position to the second
position.

67. (Amended) An intravascular therapeutic catheter as in
claim 57 wherein the catheter body has a proximal portion and
further comprising:

a fluid delivery lumen located in the catheter body
extending from the proximal portion to a position
proximate the tissue penetrating member for delivering
a fluid to the location of the tissue penetrating
member.

70. (Amended) An intravascular therapeutic catheter as in
claim 57 wherein:

the tissue penetrating member is adapted for motion about a
pivot point between the first non-penetrating position

and the second tissue penetrating position; and
the second position is defined by maximum storage of energy
in the tissue penetrating member thereby defining
motion over a limited distance.

74. (Amended) An intravascular therapeutic catheter comprising:
an elongate catheter body having a distal portion;
a tissue penetrating member disposed proximate the distal
portion, operably coupled to the elongate catheter
body, and having a first non-penetrating position and a
second tissue penetrating position; and
an actuator member disposed proximate the distal portion and
operably coupled to the tissue penetrating member, for
moving the tissue penetrating member from one of the
first or second positions to the other of the first or
second positions in a direction substantially non-
parallel to the distal portion of the catheter body,
the tissue penetrating member releasing stored energy
as the penetrating member moves from the first position
to the second position.

75. (Amended) An intravascular therapeutic catheter as in claim 74, wherein the catheter body includes a constraining lumen and the first position of the penetrating member is a constrained position where the tissue penetrating member is located within the constraining lumen, and wherein the second position is an unconstrained position where the tissue penetrating member is not constrained by the constraining lumen.

78. (Amended) An intravascular therapeutic catheter of claim 74 wherein:
the tissue penetrating member is adapted for motion about a
pivot point between the first non-penetrating position

and the second tissue penetrating position; and
the second position is defined by complete release of the
stored energy thereby defining motion over a limited
distance.

82. (Amended) An intravascular therapeutic catheter comprising:
an elongate catheter body having distal portion, and having
an axis;
a tissue penetrating member disposed proximate the distal
portion operably coupled to the elongate catheter body
and having a first non-penetrating position and a
second tissue penetrating position and having a pivot
point; and
an actuator member disposed proximate the distal portion and
operably coupled to the tissue penetrating member, for
moving the tissue penetrating member from one of the
first or second positions to the other of the first or
second positions about the pivot point in a direction
substantially non-parallel to the distal portion of the
catheter body.

83. (Amended) An intravascular therapeutic catheter as in claim
82, wherein the catheter body includes a constraining lumen and
the actuator member moves the tissue penetrating member from the
constraining lumen within the catheter.

86. (Amended) An intravascular therapeutic catheter comprising:
an elongate catheter body having a distal portion and an
axis;
a tissue penetrating member having a tissue penetrating tip
disposed at an angle relative to the axis, the angle
opening in a proximal direction and being of no more
than approximately 90 degrees, the tissue penetrating

member being disposed proximate the distal portion and operably coupled to the elongate catheter body and having a first non-penetrating position and a second tissue penetrating position; and
an actuator member disposed proximate the distal portion and operably coupled to the tissue penetrating member, for moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions in a substantially transverse path with respect to the axis.

91. (Amended) An intravascular therapeutic catheter comprising:
an elongate catheter body having a distal portion and an axis;
a tissue penetrating member having a tissue penetrating tip disposed at an angle relative to the axis, the angle opening in a proximal direction and being of no more than approximately 90 degrees, the tissue penetrating member being disposed proximate the distal portion and operably coupled to the elongate catheter body and having a first non-penetrating position and a second tissue penetrating position; and
an actuator member disposed proximate the distal portion and operably coupled to the tissue penetrating member, for moving the tissue penetrating member a limited distance from one of the first or second positions in a direction substantially non-parallel to the catheter body to the other of the first or second positions.

93. (Amended) An intravascular therapeutic catheter as in claim 91, wherein the actuator member moves the tissue penetrating member along a lateral path with respect to the axis of the catheter body.

97. (Amended) An intravascular therapeutic catheter as in claim 91, wherein the tissue penetrating member is cooled.

103. (Amended) A method for treating cardiac tissue comprising the steps of:

providing an intravascular therapeutic catheter having an elongate catheter body, an actuator and a tissue penetrating member having a tissue penetrating tip disposed at an angle relative to the axis, the angle opening in a proximal direction and being of no more than approximately 90 degrees, the tissue penetrating member being operably coupled to the catheter body and disposed proximate a distal portion of the catheter body, the tissue penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site proximate the cardiac tissue; and

adding energy to the tissue penetrating member to move the tissue penetrating member from the first position in a direction substantially non-parallel to the catheter body to the second position.

110. (Amended) A method for treating cardiac tissue comprising the steps of:

providing an intravascular therapeutic catheter having an elongate catheter body, an actuator and a tissue penetrating member operably coupled to the catheter body and disposed proximate a distal portion of the catheter body, the tissue penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site proximate the cardiac tissue; and
releasing energy from the tissue penetrating member to move the tissue penetrating member in a direction substantially non-parallel to the distal portion of the catheter body from the first position to the second position.

116. (Amended) A method for treating cardiac tissue comprising the steps of:

providing an intravascular therapeutic catheter having an elongate catheter body, an actuator and a tissue penetrating member operably coupled to the catheter body and disposed proximate a distal portion of the catheter body, the tissue penetrating member having a pivot point, a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site proximate the cardiac tissue; and

moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions about the pivot point in a direction substantially non-parallel to the distal portion of the catheter body.

117. (Amended) A method for treating cardiac tissue as in claim 116 wherein the catheter body includes a restraint lumen and the tissue penetrating member is restrainable in the restraint lumen; and

wherein the step of moving the tissue penetrating member further comprises moving the tissue penetrating member from the restraint lumen whereby the tissue penetrating member moves from one of the first or second positions

to the other of the first or second positions about the pivot point.

120. (Amended) A method for treating cardiac tissue comprising the steps of:

providing an intravascular therapeutic catheter having an elongate catheter body, an actuator and a tissue penetrating member having a tissue penetrating tip disposed at an angle relative to the axis, the angle opening in a proximal direction and being of no more than approximately 90 degrees, the tissue penetrating member being operably coupled to the catheter body and disposed proximate a distal portion of the catheter body, the tissue penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site proximate the cardiac tissue; and

moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions in a substantially transverse path with respect to a longitudinal axis of the catheter body.

125. (Amended) A method for treating cardiac tissue comprising the steps of:

providing an intravascular therapeutic catheter having an elongate catheter body, an actuator and a tissue penetrating member with a tissue penetrating tip, disposed at an angle relative to the catheter body, the angle opening in a proximal direction of no more than approximately 90 degrees, the tissue penetrating member being operable coupled to the catheter body and disposed proximate a distal portion of the catheter

body, the tissue penetrating member having a first non-penetrating position and a second tissue penetrating position;
navigating the catheter through vasculature to a treatment site proximate the cardiac tissue; and
moving the tissue penetrating member a limited distance from one of the first or second positions in a direction substantially non-parallel to the catheter body to the other of the first or second positions.

132. (Amended) A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body and a tissue penetrating member operably coupled to the catheter body and having a tissue penetrating tip disposed at an angle relative to the catheter body, the angle opening in a proximal direction of no more than approximately 90 degrees, the tissue penetrating member being disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position;
navigating the catheter through vasculature to a treatment site proximate the cardiac tissue to be treated;
moving the tissue penetrating member from one of the first or second positions in a direction substantially non-parallel to the catheter body to the other of the first or second positions; and
delivering a drug comprising a genetic material to the treatment site.

133. (Amended) A method for treating cardiac tissue as in claim 132 wherein the genetic material, when incorporated into the

tissue penetrating member, results in the expression of therapeutic materials.

139. (Amended) A method of treating cardiac tissue as in claim 132 wherein the cardiac tissue is proximate a coronary vessel having a wall and wherein the drug is delivered outside the wall of the coronary vessel.

142. (Amended) A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body and a tissue penetrating member operably coupled to the catheter body and having a tissue penetrating tip disposed at an angle relative to the catheter body, the angle opening in a proximal direction of no more than approximately 90 degrees, the tissue penetrating member being disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site proximate the cardiac tissue;

moving the tissue penetrating member from one of the first or second positions in a direction substantially non-parallel to the catheter body to the other of the first or second positions; and

delivering a drug comprising glycoprotein or a fragment thereof to the treatment site.

143. (Amended) A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body, a tissue penetrating member

operably coupled to the catheter body and disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position, and having a tissue penetrating tip disposed at an angle relative to the catheter body, the angle opening in a proximal direction of no more than approximately 90 degrees, and further having an actuator member operably coupled to the tissue penetrating member and disposed proximate a distal portion of the catheter body for moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions;

navigating the catheter through vasculature to a treatment site proximate the cardiac tissue;

actuating the tissue penetrating member whereby the tissue penetrating member moves from one of the first or second positions in a direction substantially non-parallel to the catheter body to the other of the first or second positions; and

delivering a drug to the treatment site wherein the drug is selected from the group consisting of: a peptide, a protein and a fragment thereof.

147. (Amended) A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body, a tissue penetrating member operably coupled to the catheter body and disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position, and further having an actuator member operably coupled to

the penetrating member and disposed proximate a distal portion of the catheter body for moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions;
navigating the catheter through vasculature to a treatment site proximate the cardiac tissue;
actuating the tissue penetrating member whereby the tissue penetrating member moves from one of the first or second positions in a direction substantially non-parallel to the catheter body to the other of the first or second positions; and
delivering a drug comprising a genetic material to the treatment site.

Please add new claims 164, 166, 167 and 168 as follows:

164. (New) The method of claim 132 wherein delivering comprises: delivering the drug to myocardium.

166. (New) The method of claim 147 wherein delivering comprises: delivering the drug to myocardium.

167. (New) The method of claim 142 wherein delivering a drug comprises: delivering genetic material.

168. (New) The method of claim 143 wherein delivering a drug comprises: delivering genetic material.